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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,228	11/25/2003	Michael P. Caren	10021301-1	6698

7590 11/24/2006

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EXAMINER	
CROW, ROBERT THOMAS	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 11/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/722,228	CAREN ET AL.	
	Examiner	Art Unit	
	Robert T. Crow	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 26-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 26-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 18 September 2006 in which claims 1, 3-5, 7, 9, 11, 15-16, and 21 were amended, claims 21-25 were canceled, and new claims 26-30 were added. All of the amendments have been thoroughly reviewed and entered.

The previous rejections under 35 U.S.C. 112, second paragraph, are withdrawn in view of the amendments.

The previous rejections under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) not reiterated below are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are addressed following the rejections necessitated by the amendments.

It is noted that claim 21 is listed on page 5 of the claims as "withdrawn/currently amended" and is then cancelled; therefore, claim 21 is cancelled.

Claims 1-11 and 26-30 are under prosecution.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson et al (U.S. Patent No. 6,168,948 B1, issued 2 January 2001).

Regarding claim 1, Anderson et al teach a device for conducting binding reactions. In a single exemplary embodiment, Anderson et al teach a device comprising two chambers in fluid communication; namely, a device incorporating a plurality of chambers arranged in series whereby the fluid in moved

serially through the chambers (column 22, lines 27-38). Anderson et al further teach the chambers have known varied volumes (column 18, lines 45-46); thus, at least one chamber has a greater volume than the other chamber. Anderson et al also teach the device has an analytical chamber including an oligonucleotide array at the bottom of the chamber (column 24, lines 5-6). The array has positionally distinct oligonucleotide probes attached to a substrate (column 12, lines 46-65) by tethering using chemical bonds (column 47, lines 63-65); thus, the probes are non-diffusively bound to the surface in a predetermined (i.e., positionally distinct) manner on the tethers, which are features. Anderson et al also teach the device has an amplification reaction chamber having PCR primers disposed therein (column 10, lines 15-39). Anderson et al teach the primers are tethered to a surface of the device (column 63, lines 49-51); therefore, the primers are non-diffusively bound (i.e., tethered) in a predetermined manner (i.e., on a specific surface of the device) on the tethers, which are features.

Regarding claim 2, Anderson et al teach the device of claim 2 wherein the chambers have capillary dimensions; namely, elongated reaction chambers of micron scale dimensions are used (column 18, lines 23-34).

Regarding claim 6, Anderson et al teach the device of claim 1 in communication with a detector (column 60, lines 21-47 and Figure 49).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 3, and 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al (U.S. Patent No. 6,168,948 B1, issued 2 January 2001).

Regarding claim 3, Anderson et al teach the device of claim 1 for conducting binding reactions. In a single exemplary embodiment, Anderson et al teach a device comprising two chambers in fluid communication; namely, a device incorporating a plurality of chambers arranged in series whereby the fluid in moved serially through the chambers (column 22, lines 27-38). Anderson et al further teach the chambers have known varied volumes (column 18, lines 45-46); thus, at least one chamber has a greater volume than the other chamber. Anderson et al also teach the device has an analytical chamber including an oligonucleotide array at the bottom of the chamber (column 24, lines 5-6). The array has positionally distinct oligonucleotide probes attached to a substrate (column 12, lines 46-65) by tethering using chemical bonds (column 47, lines 63-65); thus, the probes are non-diffusively bound to the surface in a predetermined (i.e., positionally distinct) manner on the tethers, which are features. Anderson et al also teach the device has an amplification reaction chamber having PCR primers disposed therein (column 10, lines 15-39). Anderson et al teach the primers are tethered to a surface of the device (column 63, lines 49-51); therefore, the primers are non-diffusively bound (i.e., tethered) in a predetermined manner (i.e., on a specific surface of the device) on the tethers, which are features.

While Anderson et al do not teach instructions, the courts have found that "[n]onfunctional descriptive material cannot render nonobvious an invention that would have otherwise been obvious. *In re Ngai*, **>367 F.3d 1336, 1339, 70 USPQ2d 1862, 1864 (Fed. Cir. 2004) (combining printed instructions and an old product into a kit will not render the claimed invention nonobvious even if the instructions detail a new use for the product). Therefore, because the courts have stated that the inclusion of instructions with an old product is obvious, the instantly claimed instructions are obvious in view of Anderson et al.

Regarding claim 7, Anderson et al an apparatus for conducting hybridization reactions. In a single exemplary embodiment; Anderson et al teach a base unit for incorporating the reaction chamber containing portion (column 34, lines 28-38) which is a housing, which further comprises elongated reaction chambers of micron scale dimensions (column 18, lines 23-34), which is an interior with capillary dimensions. Anderson et al also teach said interior comprises at least two chambers in fluid communication; namely, the device incorporates a plurality of chambers arranged in series whereby the fluid in moved serially through a plurality of chambers (column 22, lines 27-38), wherein the chambers have known varied volumes (column 18, lines 45-46); thus, at least one chamber has a greater volume than the other chamber. Anderson et al also teach the device has an analytical chamber including an oligonucleotide array at the bottom of the chamber (column 24, lines 5-6). The array has positionally distinct oligonucleotide probes attached to a substrate (column 12, lines 46-65) by tethering using chemical bonds (column 47, lines 63-65); thus, the probes are non-diffusively bound to the surface in a predetermined (i.e., positionally distinct) manner on the tethers, which are features. Anderson et al also teach the device has an amplification reaction chamber having PCR primers disposed therein (column 10, lines 15-39). Anderson et al teach the primers are tethered to a surface of the device (column 63, lines 49-51); therefore, the primers are non-diffusively bound (i.e., tethered) in a predetermined manner (i.e., on a specific surface of the device) on the tethers, which are features. Anderson et al also teach a detector in communication with said housing detector (column 60, lines 21-47 and Figure 49).

While Anderson et al do not teach the specific sizes of each chambers, Anderson et al do teach elongated chambers on the micron scale (column 18, lines 23-34), which are capillary dimensions. Anderson et al teach the chambers have known varied volumes (column 18, lines 45-46); thus, at least one chamber has a greater volume than the other chamber. Anderson et al also teach that smaller chambers cool faster than larger volume counterparts with the added advantage that the ability to change temperature rapidly allows for rapid thermal cycling reactions (e.g., PCR; column 48, lines 14-47).

It would therefore have been obvious to a person or ordinary skill in the art at the time the invention was claimed to modify the device of Anderson et al so that the PCR chamber is smaller with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in the ability to rapidly change temperatures during PCR, thereby allowing rapid PCR reactions as explicitly taught by Anderson et al (column 48, lines 14-47).

Since the PCR chamber comprises probes that are directed to target molecules having expected concentrations in a sample solution that are greater than a predetermined value, the smaller chamber therefore comprises probes that are directed to target molecules having expected concentrations in a sample solution that are greater than a predetermined value; namely, PCR requires two primer sequences (column 9, lines 15-26). The smaller PCR chamber therefore has probes for at least one copy of the sequence. Similarly, since the oligonucleotide array comprises probes that are directed to target molecules having expected concentration that are less than said predetermined value, the larger chamber comprises probes that are directed to target molecules having expected concentration that are less than said predetermined value; namely, the oligonucleotide array has all possible probes of a given length, wherein for a 12-mer target, only 5 of the 65,356 probes hybridize to the target (column 13, lines 55-60). The oligonucleotide array chamber therefore has probes for target molecules that are not present in the sample (i.e., have a concentration of zero).

Regarding claim 8, the apparatus of claim 7 is discussed above. Anderson et al also teach the apparatus wherein said housing is part of a microfluidic system; namely, a base unit for incorporating the reaction chamber containing portion (column 34, lines 28-38).

Regarding claim 9, the apparatus of claim 7 is discussed above. Anderson et al also teach the apparatus wherein said detector is a charge coupled device (column 16, lines 60-62).

Regarding claim 10, the apparatus of claim 7 is discussed above. Anderson et al also teach the apparatus further comprising a fluid dispensing device; namely, the device applies electric currents across buffer chambers to supply electrophoresis buffers (column 24, lines 27-30).

7. Claims 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al (U.S. Patent No. 6,168,948 B1, issued 2 January 2001) in view of Muller et al (U.S. Patent No. 5,804,384, issued 8 September 1998).

Regarding claim 4, Anderson et al teach the device of claim 1 for conducting binding reactions. In a single exemplary embodiment, Anderson et al teach a device comprising two chambers in fluid communication; namely, a device incorporating a plurality of chambers arranged in series whereby the fluid in moved serially through the chambers (column 22, lines 27-38). Anderson et al further teach the chambers have known varied volumes (column 18, lines 45-46); thus, at least one chamber has a greater volume than the other chamber. Anderson et al also teach the device has an analytical chamber including an oligonucleotide array at the bottom of the chamber (column 24, lines 5-6). The array has positionally distinct oligonucleotide probes attached to a substrate (column 12, lines 46-65) by tethering using chemical bonds (column 47, lines 63-65); thus, the probes are non-diffusively bound to the surface in a predetermined (i.e., positionally distinct) manner on the tethers, which are features. Anderson et al also teach the device has an amplification reaction chamber having PCR primers disposed therein (column 10, lines 15-39). Anderson et al teach the primers are tethered to a surface of the device (column 63, lines 49-

51); therefore, the primers are non-diffusively bound (i.e., tethered) in a predetermined manner (i.e., on a specific surface of the device) on the tethers, which are features.

Anderson et al teach the PCR chamber comprising probes having expected concentrations in a sample solution that are equal to or greater than a predetermined value; namely, PCR requires two primer sequences (column 9, lines 15-26). The PCR chamber therefore has probes for at least one copy of the sequence.

Anderson et al also teach the oligonucleotide array comprising probes that are directed to target molecules having expected concentration that are less than said predetermined value; namely, the array has all possible probes of a given length, wherein for a 12-mer target, only 5 of the 65,356 probes hybridize to the target (column 13, lines 55-60). The hybridization array therefore has probes for target molecules that are not present in the sample; i.e., have a concentration of zero).

While Anderson et al do not teach the specific sizes of each chambers, Anderson et al do teach elongated chambers on the micron scale (column 18, lines 23-34), which are capillary dimensions. Anderson et al teach the chambers have known varied volumes (column 18, lines 45-46); thus, at least one chamber has a greater volume than the other chamber. Anderson et al also teach that smaller chambers cool faster than larger volume counterparts with the added advantage that the ability to change temperature rapidly allows for rapid thermal cycling reactions (e.g., PCR; column 48, lines 14-47).

It would therefore have been obvious to a person or ordinary skill in the art at the time the invention was claimed to modify the device of Anderson et al so that the PCR chamber is smaller with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in the ability to rapidly change temperatures during PCR, thereby allowing rapid PCR reactions as explicitly taught by Anderson et al (column 48, lines 14-47).

Since the PCR chamber comprises probes that are directed to target molecules having expected concentrations in a sample solution that are greater than a predetermined value, the smaller chamber

therefore comprises probes that are directed to target molecules having expected concentrations in a sample solution that are greater than a predetermined value; namely, PCR requires two primer sequences (column 9, lines 15-26). The smaller PCR chamber therefore has probes for at least one copy of the sequence. Similarly, since the oligonucleotide array comprises probes that are directed to target molecules having expected concentration that are less than said predetermined value, the larger chamber comprises probes that are directed to target molecules having expected concentration that are less than said predetermined value; namely, the oligonucleotide array has all possible probes of a given length, wherein for a 12-mer target, only 5 of the 65,356 probes hybridize to the target (column 13, lines 55-60). The oligonucleotide array chamber therefore has probes for target molecules that are not present in the sample (i.e., have a concentration of zero).

Anderson et al are silent with respect to linear arrays.

However, Muller et al teach a device having capture probes specific for a target analyte wherein the probes are arranged in linear arrays (Abstract) with the added advantage that linear arrays generate signals that resemble a barcode in the device (column 1, lines 50-52).

It would therefore have been obvious to a person or ordinary skill in the art at the time the invention was claimed to have modified the arrayed devices as taught by Anderson et al with the linear arrays of Muller et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because such a modification would have resulted in generation of signals that resemble a barcode in the device as explicitly taught by Muller et al (column 1, lines 50-52).

8. Claims 1, 5, and 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al (U.S. Patent No. 6,168,948 B1, issued 2 January 2001) in view of Rovera et al (U.S. Patent No. 6,221,635 B1, issued 24 April 2001) and in view of Chenchik et al (U.S. Patent Application Publication No. US 2001/0026919 A1, published 4 October 2001).

Regarding claims 5 and 26, Anderson et al teach a device (i.e., the device of claim 1) for conducting binding reactions. In a single exemplary embodiment, Anderson et al teach a device comprising two chambers in fluid communication; namely, a device incorporating a plurality of chambers arranged in series whereby the fluid in moved serially through the chambers (column 22, lines 27-38). Anderson et al further teach the chambers have known varied volumes (column 18, lines 45-46); thus, at least one chamber has a greater volume than the other chamber. Anderson et al also teach the device has an analytical chamber including an oligonucleotide array at the bottom of the chamber (column 24, lines 5-6). The array has positionally distinct oligonucleotide probes attached to a substrate (column 12, lines 46-65) by tethering using chemical bonds (column 47, lines 63-65); thus, the probes are non-diffusively bound to the surface in a predetermined (i.e., positionally distinct) manner on the tethers, which are features. Anderson et al also teach the device has an amplification reaction chamber having PCR primers disposed therein (column 10, lines 15-39). Anderson et al teach the primers are tethered to a surface of the device (column 63, lines 49-51); therefore, the primers are non-diffusively bound (i.e., tethered) in a predetermined manner (i.e., on a specific surface of the device) on the tethers, which are features.

While Anderson et al teach a chamber having an array of PCR primers (column 10, lines 15-39) and a chamber having a hybridization array (column 24, lines 5-6), Anderson et al do not specifically teach the number of probes per feature.

However, Rovera et al teaches a microarray of PCR primers; namely, Figure 1, wherein the features of the array are spots having 2 pmol of a 20-mer oligonucleotide primer (column 4, lines 10-25). The average molecular weight of a DNA base in an oligonucleotide is 325 g/mol; therefore, the amount of primer present in each feature is approximately 13 nanograms. Rovera et al also teach the spots of the array has the added advantage of being readily crosslinkable to the substrate and provide a high specificity of sequence recognition (column 15, lines 35-40).

It would therefore have been obvious to a person or ordinary skill in the art at the time the invention was claimed to have modified the PCR primer array of the device as taught by Anderson et al with the amounts of probes per spot (i.e., feature) of Rovera et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because such a modification would have resulted in features that are readily crosslinkable to the substrate and provide a high specificity of sequence recognition as explicitly taught by Rovera et al (column 15, lines 35-40).

Neither Anderson et al not Rovera et al teach the number of probes per feature of a hybridization array.

However, Chenchik et al teach a hybridization array of oligonucleotides (Abstract), wherein the array comprises features; namely, spots on the array having oligonucleotides therein (paragraph 0106). Chenchik et al further teach the amount of oligonucleotide probe per spot is 100 nanograms or higher with the added advantage that the amount is sufficient for adequate hybridization and detection (paragraph 0097).

It would therefore have been obvious to a person or ordinary skill in the art at the time the invention was claimed to have modified the hybridization array of the device as taught by Anderson et al in view of Rovera et al with the amounts of probes per spot (i.e., feature) in the hybridization array as taught by Chenchik et al with a reasonable expectation of success. The modification would provide a greater number or probes per feature in the hybridization chamber array (i.e., 100 nanograms per spot) than the number of probes per feature in the PCR chamber array (i.e., 13 nanograms per spot). The ordinary artisan would have been motivated to make such a modification because such a modification would have resulted in an amount that is sufficient for adequate hybridization and detection as taught by Chenchik et al (paragraph 0097).

Regarding claim 27, the device of claim 26 is discussed above. Anderson et al also teach said chambers are elongated reaction chambers of micron scale dimensions are used (column 18, lines 23-34). The chambers therefore have interior capillary dimensions.

Regarding claim 28, the device of claim 26 is discussed above. Anderson et al also teach the device is in communication with a detector (column 60, lines 21-47 and Figure 49).

Regarding claim 29, the device of claim 26 is discussed above. Anderson et al also teach the device is part of a microfluidic system (Abstract)

Regarding claim 30, the apparatus of claim 7 is discussed above. Anderson et al also teach the apparatus wherein said detector is a charge coupled device (column 16, lines 60-62).

9. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al (U.S. Patent No. 6,168,948 B1, issued 2 January 2001) in view of Wu et al (U.S. Patent No. 6,221,677 B1, issued 24 April 2001).

Regarding claim 11, Anderson et al teach an apparatus for conducting hybridization reactions. In a single exemplary embodiment, Anderson et al teach at least two chambers in fluid communication; namely, the device incorporates a plurality of chambers arranged in series whereby the fluid in moved serially through the chambers (column 22, lines 27-38), wherein said chambers are elongated reaction chambers of micron scale dimensions are used (column 18, lines 23-34). The chambers therefore have interior capillary dimensions. Anderson et al also teach the chambers have known varied volumes (column 18, lines 45-46); thus, at least one chamber has a greater volume than the other chamber.

Anderson et al also teach the device has an analytical chamber including an oligonucleotide array at the bottom of the chamber (column 24, lines 5-6). The array has positionally distinct oligonucleotide probes attached to a substrate (column 12, lines 46-65) by tethering using chemical bonds (column 47, lines 63-65); thus, the probes are non-diffusively bound to the surface in a predetermined (i.e., positionally distinct) manner on the tethers, which are features. Anderson et al also teach the device has an amplification reaction chamber having PCR primers disposed therein (column 10, lines 15-39). Anderson et al teach the primers are tethered to a surface of the device (column 63, lines 49-51); therefore,

the primers are non-diffusively bound (i.e., tethered) in a predetermined manner (i.e., on a specific surface of the device) on the tethers, which are features.

. Anderson et al teach the PCR chamber comprising probes having expected concentrations in a sample solution that are equal to or greater than a predetermined value; namely, PCR requires two primer sequences (column 9, lines 15-26). The PCR chamber therefore has probes for at least one copy of the sequence.

Anderson et al also teach the oligonucleotide array comprising probes that are directed to target molecules having expected concentration that are less than said predetermined value; namely, the array has all possible probes of a given length, wherein for a 12-mer target, only 5 of the 65,356 probes hybridize to the target (column 13, lines 55-60). The hybridization array therefore has probes for target molecules that are not present in the sample; i.e., have a concentration of zero).

While Anderson et al do not teach the specific sizes of each chambers, Anderson et al do teach elongated chambers on the micron scale (column 18, lines 23-34), which are capillary dimensions. Anderson et al teach the chambers have known varied volumes (column 18, lines 45-46); thus, at least one chamber has a greater volume than the other chamber. Anderson et al also teach that smaller chambers cool faster than larger volume counterparts with the added advantage that the ability to change temperature rapidly allows for rapid thermal cycling reactions (e.g., PCR; column 48, lines 14-47).

It would therefore have been obvious to a person or ordinary skill in the art at the time the invention was claimed to modify the device of Anderson et al so that the PCR chamber is smaller with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in the ability to rapidly change temperatures during PCR, thereby allowing rapid PCR reactions as explicitly taught by Anderson et al (column 48, lines 14-47).

Since the PCR chamber comprises probes that are directed to target molecules having expected concentrations in a sample solution that are greater than a predetermined value, the smaller chamber

therefore comprises probes that are directed to target molecules having expected concentrations in a sample solution that are greater than a predetermined value; namely, PCR requires two primer sequences (column 9, lines 15-26). The smaller PCR chamber therefore has probes for at least one copy of the sequence. Similarly, since the oligonucleotide array comprises probes that are directed to target molecules having expected concentration that are less than said predetermined value, the larger chamber comprises probes that are directed to target molecules having expected concentration that are less than said predetermined value; namely, the oligonucleotide array has all possible probes of a given length, wherein for a 12-mer target, only 5 of the 65,356 probes hybridize to the target (column 13, lines 55-60). The oligonucleotide array chamber therefore has probes for target molecules that are not present in the sample (i.e., have a concentration of zero).

Anderson et al are silent with respect to linear arrays.

However, Wu et al teach an elongated web comprising a linear array of biopolymer features (e.g., a channel having single reporter beads contained therein [column 8, lines 1-16], wherein the reporter beads are sensitive to analytes; column 7, lines 8-12) wherein said linear array is from 1-5 features in width (e.g., the beads are forced into a single file; column 8, lines 10-15) with the added advantage that the linear array allows the particles to be detected in a flow cytometer detection channel (column 7, line 65-column 8, line 3).

It would therefore have been obvious to a person or ordinary skill in the art at the time the invention was claimed to have modified the arrayed devices as taught by Anderson et al with the linear arrays of Wu et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because such a modification would have resulted in allowing the particles to be detected in a flow cytometer detection channel as explicitly taught by Wu et al (column 7, line 65-column 8, line 3).

Response to Arguments

10. Applicant's arguments filed 18 September 2006 (i.e., the "Remarks") have been fully considered but they are not persuasive for the reason(s) listed below.

A. Applicant argues (e.g., on page 10-11 of the Remarks) that Anderson et al does not teach an array of features non-diffusively bound in the PCR amplification chamber, wherein the features are arranged in a pre-determined manner.

However, Anderson et al do teach the device has an amplification reaction chamber having PCR primers disposed therein (column 10, lines 15-39), and that the primers are tethered to a surface of the device (column 63, lines 49-51). Therefore, the primers are non-diffusively bound (i.e., tethered) in a predetermined manner (i.e., on a specific surface of the device) on the tethers, which are features.

B. Applicant argues on page 12 of the Remarks that the teaching of Anderson et al that smaller chambers cool faster than the larger chamber is irrelevant to the device of claim 5.

However, the teaching of Anderson et al that smaller chambers cool faster than larger volume counterparts provides an explicit motivation to make the PCR chamber comprising the array of immobilized primers smaller than the other chambers; namely, the ability to change temperature rapidly allows for rapid thermal cycling reactions, including PCR (column 48, lines 14-47).

It would therefore have been obvious to a person or ordinary skill in the art at the time the invention was claimed to modify the device of Anderson et al so that the PCR chamber is smaller with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in the ability to rapidly change temperatures during PCR, thereby allowing rapid PCR reactions as explicitly taught by Anderson et al (column 48, lines 14-47).

C. Regarding claims 4, 7, and 11, Applicant argues on pages 12-15 and pages 16-17 of the Remarks that the claims are drawn to target molecules having expected concentration that are equal to or greater than a predetermined value.

However, claims 4, 7, and 11 specifically recite the limitation "probes that are directed to target molecules having expected concentrations in a sample solution that are equal to...." The phrase at issue is sufficiently broad so as to be interpreted as "probes that are equal to or greater than a predetermined value," wherein the probes are also "directed to target molecules having expected concentrations in a sample solution;" i.e., the claim is interpreted to mean that the amount of probes is the value in question, not the value of the concentration of the target molecules. Thus, the claim has been given the broadest reasonable interpretation consistent with the specification (*In re Hyatt*, 211 F.3d1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000) (see MPEP 2111 [R-1]).

In addition, the open claim language "comprising" allows each and every chamber to have additional probes in each chamber above and beyond those required by any interpretation of the limitations recited in the claims.

D. Applicant's remaining arguments have been considered but are moot in view of the new ground(s) of rejection necessitated by the amendments.

Conclusion

11. No claim is allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

13. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing

date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert T. Crow whose telephone number is (571) 272-1113. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert T. Crow
Examiner
Art Unit 1634

JULIET C. SWITZER
PRIMARY EXAMINER